European Food Safety Authority

ENGAGEMENT & COOPERATION UNIT

Final Minutes

78th MEETING OF THE EFSA ADVISORY FORUM

Meeting details

Date 2-3 December 2020

Venue: Virtual meeting, Teams

Meeting hours: 10:00 – 13:00 (02.12.2020)

10:00 – 13:00 (03.12.2020)

Members	
Austria (AT)	Klemens Fuchs
Belgium (BE)	Benoit Horion Xavier Van Huffel
Bulgaria (BG)	Illian Kostov
Croatia (HR)	Darja Sokolić
Cyprus (CY)	Stelios Yiannopoulos Charitini Frenaritou
Czech Republic (CZ)	Jitka Götzová
Denmark (DK)	Christine Nellemann
Estonia (EE)	Piret Priisalu
Finland (FI)	Pia Mäkelä
France (FR)	Moez Sanaa Salma Elreedy
Germany (DE)	Andreas Hensel Tanjia Schwerdtle David Schumacher Nicole Gollnick
Greece (EL)	Stavros Zannopoulos
Hungary (HU)	Ákos Bernard Jóźwiak
Ireland (IE)	Pamela Byrne
Italy (IT)	Alessandra Perrella
Latvia (LV)	Vadims Bartkevičs
Lithuania (LT)	Jurgita Bakasėnienė
Luxembourg (LU)	Patrick Hau
Malta (MT)	Ingrid Busuttil
Netherlands (NL)	Antoon Opperhuizen
Poland (PL)	Jacek Postupolski
Portugal (PT)	Pedro Portugal Gaspar Filipa Melo de Vasconcelos
Romania (RO)	Simona Rădulescu
Slovenia (SI)	Urška Blaznik
Slovak Republic (SK)	Katarina Kromerova
Spain (ES)	Ana Canals Caballero
Sweden (SE)	Per Bergman

Observers & Other Participants	
Albania (AL)	Pamela Radovani
Bosnia and Herzegovina (BA)	Dzemil Hajric
Iceland (IS)	Hrönn Ólína Jörundsdóttir
Kosovo[1] (XK)	Naser Krasniqi
Montenegro (ME)	Vesna Dakovic
Norway (NO)	Cecilie Rolstad Denby Danica Grahek-Ogden
Republic of North Macedonia (MK)	Zoran Atanasov
Serbia (RS)	Tamara Bošković
Switzerland (CH)	Vincent Dudler
European Commission (Observer)	Anastasia Alvizou

EFSA Representatives	
Bernhard Url (Chair)	Donna Lucas
Juliane Kleiner	Sérgio Potier Rodeia (Advisory Forum Secretariat)
Guilhem de Seze	Cristina Alonso Andicoberry (Advisory Forum Secretariat)
Barbara Gallani	Doina Tiganu (Advisory Forum Secretariat)
Claudia Heppner	Clementina Piani (Advisory Forum Secretariat)
Marta Hugas	Angéline Camus (Advisory Forum Secretariat)

Apologies	
Turkey (TR)	Serap Hanci
Malta (MT)	Ingrid Busuttil (2nd Day)

1. Opening of the meeting & adoption of Agenda

Bernhard Url, Chair of the meeting, welcomed all members to the 78th Advisory Forum (AF) virtual meeting.

Apologies were noted from Turkey and from Malta on the second day.

Three additional items were raised under AOB:

- The transmission of data to EFSA and European Commission on Multiannual National Control Plans (LU);
- Update on the candidate Horizon Europe Partnership for the Assessment of Risks from Chemicals (PARC) (FR);
- Regular updates on activities of EFSA Scientific Networks (NL).

The Agenda was adopted.

The Chair informed that the final minutes of the 77th Advisory Forum meeting were published on EFSA website and on MS Teams on 01.12.2020.

The Chair informed the plenary that the meeting would be recorded for administrative purposes and asked if there were any objections. No objection was raised.

[1] *This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo Declaration of Independence.*

2. Update on the implementation of the new Transparency Regulation in the Food Chain

2.1 - Introduction

The Chair introduced the item summarizing the points that would be further elaborated in the presentations, namely (i) an update on documents and tools concerning the implementation of the Transparency Regulation (TR) provisions for transparency in Risk Assessment (RA); (ii) an update on partnerships with detailed presentations on TR initiatives for ensuring sustainability in RA; and iii) an update on SPIDO.

2.2 - Update on transparency in risk assessment

The Chair gave the floor to Guilhem de Seze who provided the plenary an overview on the timeline of the process of implementation of the TR. By the end of December 2020, the implementation phase should be completed. After completion, the new phase of training on the new processes will take place until March 2021.

He informed about the development of Practical Arrangements (4 documents) for: (1) public access to documents; (2) pre-submission advise, notification of studies, public consultations; (3) transparency and confidentiality by EFSA; (4) consistency of MS confidentiality assessments (PPPs). Information was also provided about the updating process of some guidance documents: 12 administrative guidance documents and 15 scientific guidance documents. A number of guidance documents are still under finalization and will be ready and published before the 27th March 2021.

Information Technology is a very important aspect of the TR since raising visibility of the different steps of the risk assessment work to stakeholders requires moving onto a more evolved electronic system. On this regard, Guilhem introduced to the plenary the IT tools involved in the implementation of the TR, including notification of studies, pre-submission advice, public access to documents, public Consultations (SALESFORCE), e-submission (FSCAP, IUCLID), risk assessment, confidentiality assessment (APPIAN), secure storage and controlled access, dissemination, proactive disclosure (MICROSOFT AZURE). The validation of these tools will be in progress until the end of December 2020. Business simulation with full dossiers will take place by March 2021.

The importance of external engagement throughout the implementation process was emphasized. EFSA will rely on the AF for dissemination of the information about the trainings in the frame of the increasing number of promotion activities involving MS and Art36 organisations. To facilitate this process, the AF will be regularly updated. The development of *ad-hoc* groups such as the Sounding Board, Technical Working Groups (NoS, IUCLID) and the DG-SANTE *ad-hoc* Advisory Group[2] will be fundamental for the good progress of the process.

Finally, further insight was given on the updated EFSA website, named "Open.EFSA", to be launched February 2021. The domain name reflects that all information will be made available to the public, including information on the risk assessment process and stages of progress.

EFSA is facing several challenges during this phase, from increased workload to changes in prioritisation and management of stakeholders' expectations on industry knowledge of e-submission requirements.

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[2] *The Advisory Group on the Food Chain and Animal and Plant Health (Advisory Group) is a group established by Decision 2004/613/EC to consult stakeholders at the European level during the preparation, revision and evaluation of EU food legislation. It provides the EC with stakeholders' views on food safety policy, and specifically on issues related to food and feed safety, labelling and presentation, human nutrition in relation to food legislation and animal health and welfare. It consists of 45 stakeholder organisations (farmers, industry, retailers, consumer and civil society representatives, etc.) that have to fulfil the requirements in the context of the EC criteria for setting up expert groups. Under this umbrella, DG-SANTE also sets up ad-hoc Working Groups to discuss more technical matters, to which representatives of non-member organisations can also be invited. This is the case at hand with the ad-hoc DG-SANTE Advisory Working Group on the Transparency Regulation implementation.*

The EC congratulated EFSA for the impressive amount of work and emphasized the continuous effort to ensure coordination with implementation at EC level. It was also highlighted that EFSA is pioneer in the discussions on opening up its work, which could however lead to potential unknown litigation that will need to be analysed and tackled at a later stage.

A question was raised from Ireland on the plan for AF members to engage in this process in 2021. Guilhem explained that engagement is expected through participation in and dissemination of trainings, as well as through continuous discussions on future improvements. The Chair stressed the importance of deepening our collaboration towards a partnership, defined as a trusted relationship based on shared values for mutual benefits, but pointed out that it is a long-term endeavour. The EC complemented by reminding the particular role of MSs in the future calls for experts, a major challenge where the AF will be asked for support.

Subsequently, France highlighted that transparency needs to be transposed at MS level, taking advantage of the experience acquired by EFSA. Germany raised questions about how the EC will communicate the new TR rules and the role of MSs in the communication strategy. The important role of MSs to participate in the communication strategy was pointed out, as trust is the result of other entities referring back to organisations. Germany complemented its intervention by stating that the concept of trust needs to be translated at MS level by communicating clearly our work to citizens.

The Chair acknowledged the importance of the points made by France and Germany. He reaffirmed that the TR brings opportunities to converge the work of MSs and EFSA and highlighted the relevance of using common tools. Concerning the process of building trust, the Chair stated that it is closely correlated with transparency creating accountability. On the question on communication of the TR, the EC highlighted that the TR includes rules to enhance communication as it is reflected in General Plan on Risk communication (implementing act). No deadline is set but the implementation of this plan is foreseen by 2023.

France asked about the process of evaluating the implementation of the TR including its impact on the trust of stakeholders in EFSA's work. Barbara Gallani emphasized that the reputation barometer could provide a blueprint to evaluate the impact as well as the increased use of analytics. The evaluation will include different criteria (relevance, coherence, efficiency, efficacy, sustainability) and to monitor the process, EFSA will be subject to an external review every 5 years.

■ 2.3 - Update on Partnerships

The Chair gave the floor to Barbara Gallani for an introduction on the topics to be developed under the update on partnerships: (A) the partnership approach; (B) the Art36 survey questionnaire; (C) follow up on the AF Task Force on Data Collection and Modelling final report; and (D) pilot projects in support of the implementation of the TR.

A. <u>The partnership approach</u>

Following discussions at the 77th AF meeting, AF members from DE, ES, FR, GR, HU, IT, NL and PT expressed their interest to support EFSA with refining the new partnership approach under development. The aim of the new AF Discussion Group on Partnerships is to better understand the expectations and the opportunities on partnerships from the perspective of MSs - on the one hand; and of the various cross-cutting challenges of the partnership framework - on the other; as well as to support EFSA in the implementation of a partnership concept. The new partnership approach will be two-tiered: (i) a close-focused approach that will look into existing and new pilot projects; and (ii) a far-focused approach that will look into the refinement of the vision and of cross-cutting aspects of its implementation - the latter to be supported by the AF Discussion Group on Partnerships.

EFSA will make arrangements for a kick-off call with the AF Discussion Group on Partnerships as soon as possible to discuss the overall vision, the respective Terms of Reference, and the expected timeline.

B. Article 36 survey questionnaire

Donna Lucas briefed the AF plenary on the outcome and the insights of the survey to Article 36 organisations on partnerships, recently carried out. The results offer a practical input to help EFSA to shape the partnership approach. It was designed to collect feedback regarding working with EFSA, specifically in relation to partnering and engagement initiatives, the administrative and financial aspects of grants and procurement, and the involvement of experts from Article 36 organisations in EFSA Panels and Working Groups. Acknowledging the quite high response rate (57% i.e. 171 out 299 respondents), Donna provided some information on the main findings, which have been internally discussed with the view to draft a practical and feasible action list. Once approved in December 2020 by the EFSA MT, the action list will be shared with the AF in an upcoming meeting.

Action point 1: EFSA to develop a final list of improvement actions stemming from the Art36 survey questionnaire and present a finalised version at an upcoming AF meeting.

C. Follow up on the Advisory Forum Task Force on Data Collection and Modelling final report

Juliane Kleiner provided a follow-up on the recommendations from the AF Task Force on Data Collection and Data Modelling final report. During the 77th Advisory Forum meeting, EFSA presented its vision for an ecosystem approach for future partnerships with MSs to ensure the sustainability of the EU food safety framework. In this context, the proposed follow-up of the AF Task Force recommendations on data was identified as a logical ecosystem platform on data. Several MSs expressed an interest, therefore, EFSA organised a teleconference (on 16th November 2020) with a core group of interested MSs (DE, FR, HU, NL) to envision next steps to translate the selected recommendations into actionable initiatives (e.g. projects). It was agreed to (i) work in parallel concerning short-term goals and a medium-term strategy; (ii) start with small projects as examples of how to implement the recommendations within a data ecosystem; and (iii) prepare a preliminary draft ToR of an Advisory Group on Data. A document containing draft ToR was shared with the AF members prior to the AF meeting, and is now open for comments until middle of January 2021 with a view to possible endorsement at the 79th AF meeting. The main objectives of the proposed Advisory Group on Data are (i) to prioritise, steer and monitor the implementation of the selected AF Task Force recommendations in the next years; (ii) to serve as a think tank for inputs on project ideas generation; and (iii) to provide input on EFSA's data roadmap in the context of EFSA Strategy for 2027.

The Chair gave the floor to Akos Jóźwiak (HU) to debrief the plenary on discussions concerning possible quick-win projects linked to Task Force recommendations. Two distinct task groups have been considered, one more vision-oriented and a second one to support EFSA in implementing the quick-wins. The proposed Advisory Group on Data would be a good fit to perform the first task, while a more operational group could perform the second one, due to its expertise on similar matters. Akos Jóźwiak also welcomed the impact of the AF Task Force work on EFSA's long-term strategic planning.

The Chair concluded this item noting the value of these outcomes for the short and long-term, developed in collaboration between EFSA and MSs. The Chair also thanked the AF Task Force on Data Collection and Modelling for creating the momentum to shape an European food safety data ecosystem, and reaffirmed the standing support of EFSA and the EC.

Action Point 2: AF members to provide feedback on the draft ToR for a new Advisory Group on Data by 15th January 2021.

D. Pilot projects in support of the Transparency Regulation

i. Proposal for a partnership on risk assessment of novel foods

Guilhem de Seze provided some background information on EFSA's remit on novel foods. The Novel Food Regulation[3] introduced a centralised assessment of the novel food dossiers by EFSA as of January 2018. Since then, a high number of dossiers has been submitted to EFSA including, 157 novel food

[3] *Regulation (EU) 2015/2283*

application dossiers and 74 dossiers in the risk assessment process. The need for increased resources due to an increase in the workload and the fact that competency on novel foods exists in the MSs who were responsible for this before the entering into force of the Regulation make of this area a good domain to build on a European partnership approach.

The proposal for a partnership on risk assessment of novel foods was therefore introduced. The overall objective of this project is to build an ecosystem with strong partnerships between EFSA and MSs for responding to the increasing workload and for the best use of scientific expertise. As the TR opens for the possibility for national scientific organisations to draft preparatory scientific opinions to be peer-reviewed and adopted by EFSA Panels, the pilot project foresees the involvement of MSs in the work of drafting scientific opinions or join a group to work on draft assessments. Those groups would be financially supported by EFSA. It was clarified that draft opinions would be submitted to the NDA Panel for review and adoption, as per usual practice.

Depending on the expertise available, the assessment could be carried out either for full dossiers within one or more categories of novel foods or only for a defined section(s) of the dossiers across the various novel food categories (*i.e.* vertical or horizontal expertise).

MSs were invited to express interest in this pilot partnership proposal to the AF Secretariat by 15th January 2021. MSs were informed EFSA will provide more details on expertise needed for this work[4].

Action Point 3: AF members to express interest to join the partnership on novel foods by 15th January 2021.

ii. Follow up on proposed partnership on enzyme safety assessment

Guilhem de Seze provided an update on the ongoing proposal for a partnership on enzyme safety assessment and reminded the plenary that the call for volunteer experts remains open until 20th December 2020. After the 77th AF meeting, interest was expressed by the following MSs: BE, EE, FR, DE, ES and DK.

Action Point 4: AF members to appoint experts for the enzymes consultation group by 20th December 2020.

During plenary discussion of Agenda item 2.3, several questions were noted. EFSA agreed to provide additional feedback on questions raised by MSs that could not be fully addressed during the plenary meeting due to lack of time - see Annex I in complement of the summary below.

Spain raised the question on the proportion of budget allocated to cooperation with Art36 organisations. The Chair indicated that the overall budget for increased cooperation is 40 million euros / year, including cooperation through grants (restricted to Art36 organisations) and procurement (open to all organisations), as well as calls related to SPIDO.

On the partnership model, Germany expressed concern regarding possible limited cooperation with those MSs with a small number of Art36 organisations – see Annex I for more information.

On the work of the AF Task Force on Data Collection and Data Modelling, concerns were raised on potential constraints for those countries with less expertise. The Chair explained that the partnership

[4] *Follow up meeting note on expertise required to perform the assessment of novel foods:*
- *Expertise in: (i) safety assessment of foods / ingredients / nutrient sources (particularly novel food / food derived from e.g. microorganisms / fungi / algae, material of mineral origin, plants, animals / insects, cell / tissue culture, engineered nanomaterials); and/or (ii) expertise in one or more of the following scientific areas: (food) chemistry / (food) biochemistry / (food) microbiology / microbiota / probiotics / food technology and processing / food composition & characterisation / exposure assessment / toxicology / human nutrition / micronutrient requirement / physiology / bioavailability.*
- *Sections of novel food dossiers are: (1) Product characterization (a. Production Process, b. Compositional data, c. Specifications); (2) Intake assessment (a. The history of use of novel food and / or its source, b. The proposed use(s) and use levels and anticipated intake); (3) Absorption, Distribution, Metabolism and Excretion (ADME), including nutrient bioavailability studies; (4) Nutritional information; (5) Toxicological information (a. Genotoxicity, b. Sub-chronic toxicity, c. Chronic toxicity and carcinogenicity, d. Reproductive and developmental toxicity); (6) Human studies; (7) Allergenicity.*

model aims at building capacity through the creation of consortia capable to transfer knowledge / experience / tools / investment from more experienced organisations to other organisations. It thus has the objective of avoiding those limitations. Moreover, it can also be explored in areas where it is particularly needed, for example, in the area of data.

Spain suggested that the AF Task Force on Data Collection and Data Modelling further invests efforts in mapping the data status of each MS, their needs and to propose solutions to address them. Spain further required clarification on the draft ToR shared ahead of meeting, namely on what is meant by the expressions (i) "the group will act as a broker", (ii) "will act as a governance body providing recommendations"; and (3) "will act as a guardian of the spirit of the AF recommendations". These questions will be considered as input under Action Item 2 above and will be clarified by the Task Force as follow up of feedback to be received by 15th January 2021.

Germany suggested that a rapporteur system could be used for the risk assessments in the new partnership model. This possibility, besides the special case of pesticides, is not foreseen in EFSA's Founding Regulation, being the scientific opinions adopted by Panels. However, EFSA reiterates its willingness / openness to build consortia for the preparation of the scientific opinions.

Spain asked whether the new partnership on novel foods, with EFSA acting as a centralised body for risk assessment, is in line with the provisions of the TR. On this regard, the EC explained that, in the case of novel foods, there was a decentralised system where risk assessment was carried out by MSs (national risk assessors, not necessarily Art36 organisations). Now (as of January 2018) there is a centralised system, with EFSA performing the assessment. In this respect, the TR provides the possibility to have preparatory work undertaken by EFSA staff or Art36 organisations, including the drafting of opinions for peer review by the Panels. Through the partnership format, EFSA seeks to retrieve that expertise at national level and to provide additional value to risk assessment.

Spain raised additional questions concerning the process of updating competences of Art36 organisations and possibilities for simplification of grant and procurement administrative procedures – see Annex I for more information.

■ 2.4 - Update on the Science Studies and Project Identification & Development Office (SPIDO)

Claudia Heppner, as a follow-up of the update on SPIDO provided at the 77th AF meeting, presented the main feedback collected during the 3rd and last phase of consultation on the four scientific theme papers, with focus on international partners (third countries and international risk assessment bodies) and stakeholders.

Participants were invited to indicate whether they support EFSA's vision and to provide suggestions for improvements. They were also consulted on their use of similar approaches and whether they see any opportunity for cooperation. The four theme papers were sent in a targeted manner to EFSA international partners and registered stakeholders. Overall, participants expressed full support to EFSA's vision on the four theme papers, as well as willingness to cooperate, especially from OECD (Organisation for Economic Cooperation and Development), Health Canada, CFSA (China National Centre for Food Safety Risk Assessment) and the US Environmental Protection Agency.

Claudia Heppner indicated that all comments provided along the process of consultations will be further evaluated by EFSA in December 2020 and subsequently shared with awarded contractors developing the roadmaps for action (May 2021). Claudia also noted the open call for tenders to develop three roadmaps for action (Building a European Partnership for Next Generation & Systems-based Environmental Risk Assessment; New Approach Methodologies in Risk Assessment; Risk Assessment of Combined Exposure to Multiple Chemicals)[5] with closing deadline set for 26th February 2021. On the latter, the Chair reiterated the importance of the support of AF and FP members in dissemination of the call and encouragement of national organisations to apply.

[5] https://etendering.ted.europa.eu/cft/cft-display.html?cftId=7613

Action Point 5: AF & FPs to support dissemination of the open call of SPIDO roadmaps recently published - deadline on 26th February 2021.

3. Engagement and Communication Update

The Chair gave the floor to Barbara Gallani to update AF members on recent communications and engagement highlights. The topic included a preview of the African Swine Fever (ASF) campaign results, an overview of stakeholders' events and updates on the ongoing animal welfare campaign, the CLEFSA campaign and the European Antibiotics Awareness Day 2020.

Barbara informed the AF about the public consultation on the draft scientific report on technical assistance in the field of risk communication closing on 17th January 2021. EFSA is therefore calling on risk communication experts and specialists to provide their comments on the report.

Czech Republic asked for clarification on plans to involve MSs in the ASF Campaign in 2021. Barbara Gallani replied that much material was developed in 2020 and the intention is to use it for an extended social media campaign in MSs and neighbouring Countries, informed by the learnings of this year's activities.

Following a request for clarification raised by Sweden, both Barbara Gallani and Guilhem de Seze confirmed that despite the creation of a Bureau, the Roundtables with NGOs and Industry have proven successful and the format has been maintained.

Finally, France asked about the work on analytics and different measurement tools used. Barbara gave a brief overview of the tools used and reminded that the work on the topic is supported by the Communication Expert Network. The Netherlands suggested the organisation of a workshop on communication and engagement analytics used by EFSA and how they can be aligned with the tools used by MS.

Action Point 6: AF & FPs to disseminate the public consultation on the draft scientific report on technical assistance in the field of risk communication – deadline on 17th January 2021.

4. Cooperation activities with MS

The Chair introduced this Agenda item which provided insights on the first year of Focal Point Network with enhanced budget, tasks and responsibilities, as well as the future steps in the framework of the new Transparency Regulation; and afterwards, a stock-taking and reflection on the way forward for the EU Risk Assessment Agenda initiative.

■ 4.1 - Focal Point network

The adoption of the Transparency Regulation and its implementation triggered the need for an evolution of Focal Point (FP) grant agreements. Barbara Gallani provided an overview of the major milestones reached and the monitoring of the latest operations introduced in 2020, namely the increased budget (up to 2M Euros, circa) and a new set of FP tasks in the field of networking and engagement, capacity building and support on data related matters.

The Chair highlighted the crucial role that the FP network can play in the sustainability pillar of the TR, especially in the new partnership ecosystem model. On the latter, the external review of the FP network, which will expectedly start in the beginning of 2021, aims at analysing the costs and benefits of the current model, investigating alternative scenarios, and identifying a future fit-for-purpose model for strengthened collaboration among MSs. Barbara Gallani asked the plenary for support at MS level during the upcoming external review.

Spain acknowledged the importance of the FP network, particularly in synergy with the AF, and announced the signature of an agreement with the National Research Agency to support the FP in mapping expertise. To conclude, Spain emphasized the timeliness of the external review to adjust the FP network with the new TR requirements and support MS.

Sweden raised the question on the main motivation for the review of the FP network and if information on the ToR for the review will be shared with AF members. Barbara confirmed that the main driver for the review is to ensure that the FP network is strengthened and fit-for-purpose for the new sustainability challenges brought by the TR. Barbara reassured the plenary that the review process will include the provision of direct input from AF members during the whole review process.

4.2 – EU Risk Assessment Agenda

In support of the EFSA Strategy 2020, EFSA and MSs agreed in 2015 to translate common food safety priority areas of work (stemming from the Delphi study) into project ideas (and subsequently into concrete projects) over the period of 2016- 2020. Such agreement developed into the EU Risk Assessment Agenda (EU-RAA). Sergio Potier Rodeia gave an overview of the past 5 years of work, the milestones achieved and the possible steps forwards to comply with the future needs of risk assessment (EU-RAA V2.0). On the latter, Sergio underlined EFSA's commitment to identify common working priorities at EU level; to re-scope the database in order to align with the new strategic frameworks (F2F, EFSA Strategy 2027); and to evolve from a database model to a more dynamic environment.

MSs expressed appreciation for the initiative and suggested to strengthen the networking element of the EU-RAA, turning the EU-RAA into a more consolidated community. Spain and Sweden pointed out the need of a platform (beyond a digital format) to foster consortia, promote funding opportunities and implement exchange among experts. In this context, Hungary and Ireland highlighted the need for more regular meetings with researchers and regulators, besides major events like RARA. Portugal made reference to a national event to be held on digital format in January 2021 with the objective of facilitating discussions and strengthen connections among experts who launched two project ideas of the EU-RAA. Particular attention was noted on the strategical value of EU-RAA and the possible link with the FP network, as well as SPIDO and EFSA research activities. Concerns were raised about the suitability of the Delphi priorities and Sweden called for new mechanisms to evaluate and identify new MS priorities that can fit best with EFSA Strategy 2027 and other overarching strategic priorities and policy environment (e.g. European Green Deal, F2F Strategy, etc.).

The Chair concluded this Agenda item acknowledging the importance of giving the EU-RAA V2.0 a clear strategic direction, ensuring complementarity with SPIDO, initiatives under the new partnership approach and DG-RTD projects. The Chair concluded by mentioning that the EU-RAA goes beyond doing risk assessment together, and that it aims at preparing, innovating, developing methodologies, collecting data and addressing risk assessment needs – which requires a strengthened community approach. Further reflections will continue to be carried out in EFSA and, once a concrete way forward is defined, the item will be brought back to plenary discussion.

5. Risk Assessment

5.1 - BfR draft mandate on vanadium

The Chair gave the floor to David Schumacher, from the Unit on Residues of the Department for Safety in the Food Chain in BfR, who presented the BfR draft mandate on vanadium.

In the context of a request raised by the German Federal Ministry of Food and Agriculture (BMEL) to conduct a risk assessment of levels reported for mineral waters, high concentrations of vanadium were detected. David Schumacher noted the absence of EU-harmonized standards for drinking water and mineral water and the lack of vanadium in food contaminant regulations. Moreover, currently there is no toxicological assessment deriving health-based guidance values (HBGV) by EFSA or WHO/FAO (JECFA). However, it was identified that vanadium compounds exert adverse toxicological effects (e.g.

carcinogenicity, mutagenicity, reproductive toxicity) and may be present in food. In 2004, vanadium was assessed by EFSA's NDA Panel, which concluded that data were inadequate to derive an upper intake level.

Juliane Kleiner provided a summary of the procedure followed to date. When the draft mandate was received by EFSA, a meeting was organized between BfR and EFSA and it was agreed to provide further details and to bring the discussion to the AF in order to investigate MS priorities on the matter. Further reflections are needed in order to decide whether to assess vanadium at this stage, also taking into account the ongoing toxicology study being carried out by the US National Toxicology Program (NTP) and the current limited resources in the EFSA CONTAM Team.

Luxembourg mentioned to have some data on migration of vanadium. Sweden noted that higher consumption of surface waters suspected of carrying high level of vanadium may pose a risk to human health.

The plenary agreed to wait for more information on the progress of the NTP study and for additional MS input in order to frame a way forward. BfR is asked hold, for now, the official submission of this mandate to EFSA until further discussions in 2021.

Action Point 7: MS to share any information on vanadium available at national level.

Action Point 8: EFSA to liaise with US-NTP to gather information on the progress of the studies on vanadium.

■ 5.2 - EFSA Mandates, MS RA Plans, upcoming public consultations

Guilhem de Seze provided an update on the mandates for regulated products.

In the area of food contact materials, five mandates were received on recycling processes for plastic food contact material, which represent a big part of the workload in that area. Moreover, a mandate from DG-SANTE on phthalates has been received. The EC has asked EFSA to work with ECHA in an integrated manner in defining the groups of chemicals that need to be assessed in the context of food contact materials. This mandate is of importance due to the number and use of substances to assess. It is also the first time EFSA will apply so closely the concept of one substance-one assessment.

In the area of pesticides, two important mandates were highlighted: (i) on a scientific opinion on testing and interpretation of in-vitro comparative metabolisms studies; and (ii) on emergency authorizations for the continuous use of neonicotinoids, with the objective for EFSA to assess 21 requests for emergency authorizations coming from 10 different MSs. The latter assessment should be finalised in September 2021. An additional update was provided concerning the applications on cannabidiol as novel food. Following the conclusions of the European Court of Justice[6] stating that cannabidiol is not a narcotic, a number of dossiers for novel foods containing cannabidiol are expected to be soon submitted to EFSA. Some MSs raised concerns on the timeline for the assessment of novel food applications on cannabidiol. EFSA informed that, following the submission of the dossier, assessments will be carried out within the 9 months legal deadline.

Juliane Kleiner updated AF members about the mandates within the Risk Assessment and Scientific Assistance Department domain. In the field of contaminants, Juliane noted (i) an update on mineral oil hydrocarbons, thanking Germany for offering a thematic grant expert; (ii) on polychlorinated naphthalene; and (iii) on nitrosamines. A request for an EFSA/ECDC rapid outbreak assessment was as well received on the multi-country outbreak of *Salmonella enteritis* linked to frozen poultry (output due by 20th January 2021). Finally, reference to a mandate for an EFSA/EMA joint development of a common approach on exposure assessment methodologies for veterinary trace residues, feed additives and pesticides residues, including checking the compatibility of the approach with internationally used approaches.

[6] *Reference:* https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62018CJ0663&qid=1607529798127&from=FR

On MS mandates, Guilhem de Seze noted particular EFSA interest on three mandates: on the risk assessment of D-ribose (from NO); and two mandates in the area of pesticides (from GR): (i) on sublethal effect of sulfoxaflor; and (ii) on the effect of the use of pesticides against olive flies on bee keeping and pollinators. Any work on this field is of particular interest, as EFSA is in the process of updating its Bee Guidance.

Juliane Kleiner started by thanking NO for notifying the AF about the case of Chronic Wasting Disease in wild reindeer, and that a risk assessment is now being conducted (publication planned on the 20th January 2021). Juliane noted particular EFSA interest on the work of Finland in the zoonotic threat of the new coronavirus in mink farms and mentioned that EFSA contributed to the recent ECDC rapid risk assessment on this topic.

Finally, Juliane Kleiner informed the AF about an upcoming public consultation on the draft EFSA Scientific Committee Opinion on biological plausibility of non-monotonic dose responses and their impact on the risk assessment, to be published on the 4th of December 2020 and to run until the 4th of February 2021.

Action Point 9: EFSA invites MS to participate in the Consultation on draft EFSA Scientific Committee Opinion on biological plausibility of non-monotonic dose responses and their impact on the risk assessment, from 4th December 2020 until 4th February 2021.

6. Any Other Business (AOB)

6.1 - Update on the composition of the Member State Advisory Board of EFSA's 4th Scientific Conference and next steps

Following the invitation to express interest to join the MS Advisory Board of EFSA's 4th Scientific Conference during the 77th AF meeting, replies were received from nine countries (DE, DK, FR, IE, IS, HR, HU, NL and SK). The first meeting of the Board will be organised in the first quarter of 2021, before the March AF meeting. The Board will be Chaired by one of the MS members and co-Chaired by EFSA's Chief Scientist. The Chair of the Board will report on progress during AF meetings. The duration of the Board's mandate is approximately two years, from December 2020 to November 2022, including the time needed for preparing a possible EFSA Journal Special Issue on the Conference.

6.2 - Update from the AFDG on Capacity Building

The Chair gave the floor to Nicole Gollnick (DE) who debriefed AF members on the progress of the work of the AF Discussion Group on Capacity Building. Nicole informed the plenary about the establishment of a Steering Committee, which includes Denmark, Germany, Greece, Hungary, Italy, the Netherlands, Spain, with the EC as an Observer and EFSA as support. This Committee will meet regularly to establish the requirements of the feasibility study for an excellence label in food safety risk assessment as well as the criteria and curriculum for the excellence label. A meeting on the former took place on 25th November 2020, where EFSA informed the group that a framework contract had been identified and a first draft proposal for the feasibility study requirements was presented. The draft proposal for the feasibility study requirements will be refined taking into account the tender specifications in the EFSA framework contract. Nicole Gollnick also informed the plenary about a meeting to take place on 4th December 2020 on the excellence label criteria and curriculum (a sub-group of the Steering Committee) with the aim to elaborate a first draft. The foreseen timeline is to have the feasibility study contracted out early in spring next year.

6.3 - Update on RARA21

Pamela Byrne (IE) and Marta Hugas provided an update on the organisation of RARA21. Pamela Byrne thanked the Programme Committee for the progress made to develop the programme. The draft programme, including three Parallel sessions, is under finalisation. The process of speakers' identification is still ongoing. The need for networking to be facilitated during the RARA21 event was

re-stated. The best way to proceed will eventually depend on the format of the meeting. A decision to meet physically or not is expected to be taken in January 2021, in line with the format chosen for the AF and FP meetings happening back-to-back with the event in June 2021. The Chair reminded that RARA is a standing Agenda item at AF meetings, so the AF will follow progress closely.

■ 6.4 - Other topics raised under AOB

6.4.1 - Transmission of data to EFSA and European Commission on Multiannual National Control Plans (LU)

Luxembourg noted the issues experienced in reporting of data under the official controls, linked with the need to report data to the EC. It was indicated that some data already shared with EFSA should be transmitted to the EC. Moreover, the problem of different deadlines for the reporting of data was raised. It was proposed to set uniform deadlines for the transmission of data to EFSA and that the tools for transmission of data to the EC remain open from 1st April of each year until 1st July. A request was also formulated to have all changes in data format transmission communicated before the reporting of data in April.

Juliane Kleiner assured that EFSA and the EC try to avoid double reporting and that a web service was introduced to directly link relevant data sent to EFSA with the annual report on official controls. Concerning the issue of the deadlines, EFSA proposed to anticipate the deadlines for reporting data to EFSA to the end of June for contaminants and for pesticides, although it was noted that other MSs may have difficulties with the anticipation of the deadlines due to the COVID-19 pandemic context.

The Chair suggested that follow-up on the matter is ensured between the EC, Juliane Kleiner and MSs to look for possible solutions to avoid double reporting of data to EFSA and to the EC.

Action Point 10: EFSA to follow-up with the EC to put forward possible solutions to avoid double reporting of data to EFSA (within the frame of annual monitoring data reporting) and to the EC (within the frame of annual reports on official controls)[7].

6.4.2 – Update on the candidate Horizon Europe Partnership for the Assessment of Risks from Chemicals (PARC) (FR)

France gave an update on the progress made in the framework of the PARC initiative. Salma Elreedy informed the AF that the Steering Group put in place by DG-RTD held its last meeting, virtually, on 4th November 2020, to transition to the future governance structure of the partnership. The two interim governance bodies – the Governing Board – GB - (composed of a Country Board and an EU Board) and the Grant Signatory Board – GSB - met virtually on 1st December 2020. The objective of the meeting was to launch these interim governance bodies by presenting all the work that has been conducted over the past few months for defining PARC's future priorities and what will be its Strategic research agenda. The meetings counted with the participation of interested MSs and different EC DGs (DG-ENVI, DG-RTD, DG-SANTE, DG-GROW, JRC) and EU Agencies (EFSA, EEA, ECHA). Additional information can be provided by France (ANSES being the future coordinator of PARC). France also suggested that a presentation by EFSA on its participation in future Horizon Europe partnerships could be planned in an upcoming AF meeting. The Chair thanked France for this highly relevant update and proposed to follow-up on the possibility to have deeper discussions on the PARC initiative in future AF meetings.

[7] *Post-meeting note: a follow-up teleconference took place between EFSA and EC (SANTE D1, F7, E2, E4) on 15th December to discuss the issue raised by Luxembourg. It was agreed that the proposed solution to avoid double reporting by MSs to EFSA and the EC linked to different reporting deadlines in different legislation - discussed at the 3rd meeting of the Network on Chemical Monitoring Data Collection – is applied before a possible amendment to regulatory reporting deadlines is considered.*

6.4.3 – Regular updates on activities of EFSA Scientific Networks (NL)

The Netherlands suggested that regular updates on the activities of EFSA scientific networks are provided in upcoming AF meetings. The suggestion was agreed in plenary and will be taken aboard, whenever possible, in future meetings.

Closure of meeting

After an overview of upcoming AF meetings for 2021, the Chair closed the 78th AF meeting summarizing the main action points agreed during the two-day AF session and thanking participants for their contributions and productive meeting. The Chair, jointly with EFSA management and the AF Secretariat, wished all AF members and Observers a Merry Christmas and a Happy and Safe 2021.

LIST OF ACTION ITEMS

Reference	Who	What
Action 1	EFSA	To develop a final list of improvement actions stemming from the Art36 survey questionnaire and present a finalised version at an upcoming AF meeting
Action 2	AF members	provide feedback on the draft ToR for a new Advisory Group on Data by 15th January 2021
Action 3	AF members	To express interest to join the partnership on novel foods by 15th January 2021
Action 4	AF members	To appoint experts for the enzymes consultation group by 20th December 2020
Action 5	AF members (& FPs)	To support dissemination of the open call of SPIDO roadmaps recently published - deadline 26th February 2021
Action 6	AF members (& FPs)	To disseminate the public consultation on the draft scientific report on technical assistance in the field of risk communication – deadline by 17th February 2021
Action 7	MSs	To share with EFSA any information on vanadium available at national level
Action 8	EFSA	To liaise with US-NTP to gather information on the progress of the studies on vanadium
Action 9	MS	(EFSA invites MS) To participate in the Consultation on draft EFSA Scientific Committee Opinion on biological plausibility of non-monotonic dose responses and their impact on the risk assessment, from 04th December 2020 until 04th February 2021
Action 10	EFSA	To follow-up with the EC to put forward possible solutions to avoid double reporting of data to EFSA (within the frame of annual reporting of monitoring data) and to the EC (within the frame of annual reports on official controls submitted by MSs)

ANNEX I

Follow up on questions raised during discussion of Agenda item 2.3

1. On Article 36 competencies:

Adding a new competence for an organisation already included in the Art36 List is considered a substantial change in the designation of an organisation by the MS and therefore requires a new designation procedure.

The inclusion of organisations in the Art36 List is based on MS designations (Regulation (EC) No. 2230/2004), requiring indication of the organisation's details, evidence on compliance with the criteria and details of the specific fields of competence (Article 1 (2) of the abovementioned Regulation). Therefore, if an organisation included in the List has a new competence to be added, this needs to be formally communicated to EFSA by the MS. This is mainly due to the need for completing / confirming the evidence demonstrated for the additional competence to be added - that could be e.g. a formal change of the organisation's founding documents or simple addition of competence.

Technically, to add a new competence and information about the relevant contact person(s) in the Art36 tool, the first step is to generate a change / update request. Focal Points can then proceed with the update process, as a substantial change, based on the information received from the organisation and after the respective validation at national level. This can be achieved by simply editing the previous MS assessment summary. Focal Points can then facilitate a new formal designation to EFSA via the Permanent Representation to the EU in Brussels. The new (updated) designation received will then be tabled for approval by the EFSA Management Board and subsequently, once approved, the organisation's profile will be updated.

2. On subcontracting rules:

Provisions on subcontracting are laid down in the EU Financial Regulation as summarised below:

SUBCONTRACTING IN PROCUREMENT – Provisions in the Financial Regulation are clear and it is supported in relevant case law that tenderers when submitting bids can rely on the use of subcontracting. The contracting authority cannot exclude or limit the share of subcontracting but it can request to know the volume of subcontracting proposed for the implementation of the contract as well as requiring clear identification of the roles, activities and responsibilities of subcontractor(s). There is some scope in the FR allowing the contracting authority to require 'critical tasks' to be performed by the tenderer itself and not subcontractors but this provision is to be used exceptionally as it could be considered as a restriction on the freedom of enterprise.

SUBCONTRACTING IN GRANTS – Whilst subcontracting is permitted within the Financial Regulation for EU grants, EFSA's particular limitation on the organisations to which it can award grants (i.e. only to organisations on the Article 36 list) does mean we have to place some limitations on subcontracting in EFSA grants. So whilst any type of ancillary task to be performed under the grant agreement could be subcontracted by the beneficiary, core tasks may not be subcontracted, otherwise this would circumvent the requirement for the organisation to be on the Article 36 list if the core activities to be carried out in the project could be given to subcontractors. In EFSA grants, subcontracting is therefore limited to only ancillary and assistance tasks.

3. Limited opportunities for MSs with a lower number of Art36 organisations

Regarding the concern raised on limited opportunities for cooperation with those MSs with a small number of Art36 organisations, the partnership model also includes individual experts who, in many cases, do not belong to Art36 organisations. Moreover, it is not in the spirit of the partnership approach to ask MSs to increase the number of organisations in the Art36 List if they do not wish so, although for EFSA it is important to find the needed competencies in the List.